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INTERNATIONAL ISSUES

TURKEY

In December 2008, Turkey enacted the Inventory and Control of Chemicals Regulation, a scaled-down version of the European Union's REACH regulation to establish an inventory of chemicals produced and imported into Turkey and to better control potential risks posed by those chemical substances. Adoption of the regulation is one of many steps Turkey is required to take to secure membership in the European Union. The authors of this article advise chemical manufacturers and importers to obtain as much information as possible on the regulation and its implementation and to stay abreast of forthcoming clarifications.

Turkey Enacts REACH-Like Chemical Program: What Stakeholders Need to Know

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Turkey enacted the Inventory and Control of Chemicals Regulation (Regulation) in December 2008. The Regulation is a scaled-down version of the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation and mandates the creation of a chemical inventory for manufactured and imported substances in Turkey.

For a variety of reasons, the new law is the source of considerable confusion. This article seeks to clarify several issues and to assist stakeholders in understanding the new Regulation's application and effect.

Background

As part of its quest to become a full member of the European Union, Turkey must successfully demonstrate acceptance of the rights and obligations arising under the EU system and its institutional governance framework.

Turkey has been an associate EU member since 1963 and submitted its application for full membership in 1987. Formal "accession" negotiations were opened with Turkey in October 2005.

Among the many components of the "acquis" of the Union—the European Union's rights, obligations, and institutional framework—are chapters on environment, consumer and health protection, and related topics with

which Turkey must be aligned to satisfy as a prerequisite of accession. Adoption of the Regulation is one of many measures Turkey is required to take to secure EU membership.

Importantly, on November 10, 2009, the Turkish government issued an Amendment to the Regulation. As of this writing, an official English translation of the Amendment is not yet available. Based on information from various reliable sources, it appears that the date for notification of substances in quantities greater than one metric ton and less than 1,000 metric tons, and greater than 1,000 metric tons (Articles 7 and 8 of the Regulation, as explained below) has been extended from December 26, 2009, to June 30, 2010. This is good news and provides time for some much needed clarification on the application of the Regulation.

The New REACH-Like Law

The Regulation is intended to achieve two key goals: to establish an inventory of chemicals produced and imported into Turkey and to better control potential risks posed by those chemical substances.

The chemical inventory takes into consideration substances already considered “notified” in the European Union before and after September 18, 1981, existing and new substances, respectively. The Regulation establishes a mechanism to facilitate data collection, chemical prioritization, and control of substances in commerce with the ultimate goal of reducing potential risks posed by substances manufactured in or imported into Turkey.

Notification: The Regulation requires that entities importing into or manufacturing in Turkey existing and new chemical substances, alone or in preparations and in quantities above one ton per year, submit certain information on these substances to the Ministry of Environment and Forestry for inclusion on the inventory.

Like REACH, the data elements that must be included in the notification differ depending on tonnage. Unlike REACH, the amount of data initially required to be submitted is more limited.

It appears that notifiers under the Turkish Regulation are not initially required to generate new data should data gaps be found to exist, although this is a distinction yet to be confirmed in practice. At this time, it is unclear how the Authorities intend to address data gaps.

As is typical with chemical regulatory programs, once the data are reviewed by the Authorities, if a data gap is identified, the Authorities may seek to fill the gap by requesting additional data or requesting the generation of new data.

Timing: As noted above, the Amendment appears to have pushed back the notification date from December 26, 2009, to June 30, 2010. This apparent delay provides a much-needed opportunity for stakeholders to assess how the new provisions impact operations and thus to ensure compliance by the June deadline.

Notification Elements: While only basic information is required for substances imported or manufactured in quantities between one to 1,000 tons per year, more substantial information must be submitted for substances imported or manufactured annually in quantities above 1,000 tons.

Under the Regulation, the Ministry may also require additional information regarding the physicochemical,

toxicological, and ecotoxicological characteristics in relation to the risk assessment of substances. This authority introduces additional uncertainty as it seems that the ministry has discretion as to when and how it may request such information.

Confidentiality: A manufacturer or importer may assert a claim of confidentiality by submitting a request for confidentiality to the Turkish Ministry of Environment and Forestry. It is unclear, however, what actual protections are in place to prevent the public dissemination of data and information claimed confidential. It is equally unclear what exactly the criteria are for granting requests for confidentiality.

Article 12(2) is clear, however, about what categories of information cannot be claimed confidential.¹ The approval of any confidentiality claim will be provided in writing by the Ministry of Environment and Forestry. This issue is particularly important in view of the pending discussions related to the value of “published data” under REACH, in the European Union, since data published by the Ministry as a result of the Regulation may lose some of its value for purposes of REACH in the European Union.

New Information: Notifiers are also required under the Regulation to update information submitted to the Ministry under certain circumstances.

The notifier is required to update the Ministry of: any change in a substance’s use pattern that results in a substantial change in exposures to man and/or the environment; any newly acquired data pertinent to the substance that may be relevant to risk assessment or that would support the substance as being of high risk to human health and/or the environment; any change in the classification of the substance; and/or any change in the quantities imported or manufactured.

None of these changes is very well defined in terms of scope or magnitude, so it remains to be seen what degree of change can be expected to trigger a reporting obligation.

¹ Article 12: (1) If manufacturer or importer considers that there is a confidentiality problem, he may indicate the information provided for in Articles 7, 8, and 11 which he considers to be commercially sensitive and disclosure of which might harm him industrially or commercially, and he may request from Ministry to be kept secret all information from third parties in writing. If the manufacturer or importer subsequently discloses himself information considered before as being confidential, he will inform the Ministry thereof. (2) Industrial and commercial secrecy shall not apply to: (a) the name of the substance, as given in the European Inventory of Existing Commercial Substances and the European List of Notified Chemical Substances; (b) the name of the manufacturer or importer; (c) data on physico-chemical properties of the substance and on pathways and environmental fate; (d) the summary results of the toxicological and ecotoxicological tests, in particular data on carcinogenicity, mutagenicity and/or the substance’s toxicity for reproduction; (e) any information relating to the methods and precautions relating to the substance and the emergency measures; (f) any information which, if withheld, might lead to animal experiments being carried out or repeated needlessly; (g) analytical methods that make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans to the substance. (3) Ministry, depending on first paragraph, informs manufacturer or importer about decision within 15 days after receiving the application for confidentiality. (4) Acceptance of confidentiality is subject to written approval of Ministry.

Multiple Manufacturers: If a chemical substance is manufactured or imported by more than one manufacturer or importer, the Regulation seems to suggest that the notification/submission may be made by only one of the parties that manufactures or imports the substance on behalf of all others.

Few details are provided in the Regulation of the multi-party notification procedure and it is unclear how this procedure will operate. This, again, may have been included to mirror the REACH principle “one substance, one registration,” but it lacks details allowing companies to anticipate how such requirement or possibility may work in practice.

Polymers: The Regulation itself does not specify whether polymers are included within its scope. The Amendment, however, specifically excludes polymers from the data reporting requirements contained within the Regulation. Thus, although polymers are clearly exempt from the data reporting requirements, it appears that the other provisions within the Regulation and the Amendment apply to polymers.

Until confirmation from the Turkish Authorities can be obtained, however, it is difficult to ascertain the precise impact of these changes.

Prioritization: Article 13 of the Regulation requires the Ministry to establish a priority list of substances or substance groups that require more specific and immediate attention due to their potential effects on human health and the environment or lack of available information. This list is similar to the REACH Candidate and the Annex XIV lists.

Under the Regulation, substances that are carcinogenic, mutagenic, and/or toxic for reproduction will receive specific scrutiny. Priority list substances will undergo a risk assessment, and the notifier may be required to provide further information. Thus, differently from REACH, the Turkish authorities will perform the risk assessment of priority substances themselves, much like the previously applicable system in the European Union, under the Existing Substances Regulation 793/93.

Implementation Challenges

Although the Regulation was issued almost a year ago, only limited information is available on it and details on the specific obligations the Regulation imposes on stakeholders in the chemical community remain sketchy. As a result, there are currently many unanswered questions regarding the Regulation’s application and implementation. Key issues that need resolution include the following.

The Regulation appears to allow one manufacturer or importer, with the agreement of the others, to submit a notification to the Ministry on behalf of other manufacturers and importers of the same substance. The Regulation does not, however, provide a mechanism by which manufacturers or importers can learn of notifications for substances submitted by others, and how data submitted by some can or will be shared with competitors (e.g., it is unclear whether there will be mandatory data sharing, similar to REACH).

Similarly, there is little guidance provided on how suppliers should work with downstream users and other interested stakeholders to learn who is doing what to ensure efficiency.

The utility of this “group submission” feature therefore appears somewhat limited and may, as a practical matter, be of value only to those entities or business sectors that have a well-defined supplier/downstream user relationship. It could also be that this function will be facilitated by the development of the information technology (IT) system discussed below.

Unless this feature is clarified soon by Turkish Authorities, the Ministry may receive multiple and unhelpful notifications for each substance for which a notification is required.

Currently the Regulation does not specify the format in which the actual endpoint data are to be submitted to the Ministry under Articles 7 and 8. Notifiers are merely encouraged to use the “chemical program package on the website of the Ministry.”

Most global chemical programs request that endpoint data be submitted in a robust study format that includes the assessment and assignment of the data with a reliability score, which typically follows a scheme such as that recommended by Klimisch.² Experience with other global chemical programs, including the U.S. High Production Volume (HPV) Challenge Program, the Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) Program, and REACH (to date), has demonstrated the need for an indication of the reliability of the data submitted.

Although the issue is still debated, most stakeholders agree that reliability codes play an integral part in streamlining the data collection and review process and ensure that data needed to characterize a substance’s hazard potential are properly identified. Without this requirement in the Regulation or appropriately established Guidance documents, it is unclear how the Ministry will be able to assess and collate the data it receives and ultimately to determine which data are best suited to assess the hazard associated with a particular chemical and to manage efficiently any potential risk the substance may pose.

In addition, there is no requirement that notifiers provide more than one data entry per endpoint for the data identified in Articles 7 or 8, regardless of whether the notifier has within its possession multiple studies or other reliable references that may be useful for chemical assessment purposes. We note, however, that the term “research” was added by the Amendment, a term which some suggest that notifiers are expected to undertake literature searches and to submit all relevant data found in association with a particular substance. This interpretation, however, has not been confirmed with the Authorities and the provision requires clarification.

In general, the method of collecting and/or assessing screening level data to assess priorities is consistent with data collection programs enacted elsewhere.

For example, Environment Canada and Health Canada use a slightly different approach when assessing substances under the Canadian Environmental Protection Act 1999 (CEPA). Both Environment Canada and Health Canada perform extensive literature searches and modeling exercises to populate Canada’s Priority Substance List.

² Klimisch, H.J., Andreae, E., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and ecotoxicological data. *Reg. Toxicol. Pharmacol.* 25:1-5.

Similarly, the U.S. HPV Challenge Program asked submitters to provide relevant data on a chemical substance to ensure that each required endpoint is addressed, however, there was no requirement to submit *all* relevant and available data. The OECD SIDS Program encourages participants to prepare a comprehensive dossier, at a minimum for the required endpoints, which distinguishes each study's relevance by assigning reliability codes.

Each of the above approaches has been successful, yet in the case of Canadian and the U.S. programs, the ability to establish a priority list has been time consuming and required financial commitment from government agencies.

Given the desire to encourage industry to take a more active role in assessing the hazard potential of the chemicals they bring to market, government agencies may benefit from receipt of notifications that consider *all* publicly available data and unpublished data.

In Turkey, the inherent ambiguity in what notifiers are required to submit could impose significant burdens on the government to complete comprehensive literature searches and, in some cases, modeling exercises to ensure that sufficient data are available to characterize the hazard and thus to assess the risk of substances notified under the Regulation.

Another issue that could benefit from clarification is the format that should be used for notifications made under the Regulation. Article 10 requires that all notifications are performed using the "chemical program package on the website of the Ministry in order to provide the information requested by Article 7 and Article 8 Paragraph 1." At this time, however, the IT system is not fully operational. Training and guidance documents also are not available.³

As the Regulation is in part motivated by Turkey's desire to become a member of the European Union, it would be desirable if the Ministry mandates that data be submitted in conformance with International Uniform Chemical Database (IUCLID) version 5, which is publicly accessible and widely used. This is the format data must be submitted under REACH and is the preferred format of the OECD SIDS Program.

In IUCLIDv5, submitter information and robust study summaries are well defined. The Authorities may wish to consider developing an IUCLIDv5 module that allows for the submission of data requested under Articles 7 and 8.

Another area where clarification is needed involves the ability of a non-Turkish entity to notify the Ministry. Currently, the Regulation specifies that a manufacturer or importer may undertake the notification if both are defined as being a real and legal person who manufactures or imports, respectively.

Under both the U.S. Environmental Protection Agency's Toxic Substances Control Act and the European Union's REACH legislation, manufacturers and importers must be located within those respective jurisdictions to submit data. Currently, however, it is unclear if the Turkish Authorities intend to allow "real and legal"

³ For more information on the IT data reporting system, see the Turkish Ministry of the Environment and Forestry at <http://www.kimyasallar.cevreorman.gov.tr/sources/default.asp>.

persons located outside of Turkey to submit a notification. As the Turkish legislation is likely to apply in a similar manner to that of the Toxic Substances Control Act and REACH, this is unlikely to be the case.

The Regulation is also silent regarding whether a non-Turkish-based entity may identify a third party to perform a notification on its behalf to protect confidential business information from downstream users (importers). Nor does the Regulation include a mechanism enabling entities outside Turkey to notify by way of a third party (such as by the REACH "only representative" mechanism).⁴

Given the lack of jurisdictional clarification and the absence of provisions under the Regulation establishing a third party entity for notification purposes, it is unclear what entities can submit the notification to the Ministry.

The Regulation does not specify the language in which the notification must be performed nor does it specify when the notification "chemical program package" will be fully operational. It is also not clear if the Ministry will accept notifications and submissions in English. This is particularly important for exporters to Turkey since many exporters to Turkey are likely to be based in the European Union and may use English for their submissions.

Practical Tips

During this early stage where much confusion abounds, businesses may wish to consider taking several steps to assure continuous business operations.

First, chemical stakeholders should review the Regulation and Amendment carefully and understand how they apply to their operations.

Second, chemical stakeholders should determine which products (at the substance level) are entering Turkey's commercial market in excess of one metric ton. Turkey has not offered guidance on this subject, but this can be done in the same manner as determining tonnage volume under REACH. At a minimum, the data requested in association with the original Regulation, dated December 26, 2008, should be collected and maintained.

Third, chemical stakeholders should try to obtain as much information as possible on the Regulation and its implementation and stay abreast of forthcoming clarifications offered by the Turkish Authorities.

As is always the case with any new chemical management program, stakeholders must seek to comply with all relevant provisions and do the best they can in the face of ambiguity and uncertainty. At the least, developing and maintaining a strong record of the effort expended to achieve compliance and to fulfill the spirit, if not the letter of the law, will go a long way in achieving success.

⁴ In the European Union, the only representative mechanism allows for a non-EU entity to appoint an only representative in the European Union to act on its behalf and to perform a registration, provided certain criteria are met.

⁵ See ECHA, Guidance on registration at 27, Section 1.6.2, Calculation of the volume to be registered, available at http://guidance.echa.europa.eu/docs/guidance_document/registration_en.pdf.

